NORTHSIDE HOSPITAL

Patrick K. Lynch
Director, BioMedical Engineering

February 22, 2000

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061 (HFA-305)
Rockville, MD 20852

Re: Docket No. 99D-4130 – Comments on Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-Ray Systems and reply to Siemens Corporation letter of December 22, 1999.

Dear Sir or Madam:

Northside Hospital is a not-for-profit hospital, located in Atlanta, Georgia. We, like every other hospital in America are involved in trying to hold down healthcare costs and comply with all Federal and State laws while providing the quality and diversity of services that our patients, physicians, and community demand. It is not an easy task. Strong enforcement of 21CFR 1020.30-33 by the FDA, as it is currently written would assure compliance with the performance standards by all manufacturers and others and provide a safer environment for patients, and others. Any modification

99D-4130 C H

of these performance standards should reflect the current state today's technology.

Let me state here that I am speaking primarily for the in-house bio medical engineers – the full-time employee of the owner of the equipment. But while I support the reduced cost distribution of diagnostic information and full compliance with the laws contained in 21CFR, I realize that there are issues concerning third-party servicers which are best addressed by those entities. Let me speak to that which I know first hand.

I have expended significant consultant's fees over the past 2 years in an attempt to purchase from the manufacturers of medical X-ray, CT scanners, lasers, and other medical equipment materials that are responsive to 21CFR 1020-50. My efforts have met with measured success, and quite a lot of frustration. The manufacturers are engaged in every sort of underhanded stalling technique imaginable to delay, mislead and ultimately deny access to materials necessary to comply with the laws contained in 21CFR. They fail to cooperate and be truthful as to their obligations under 21CFR in every way. In fact, some companies have re-printed manuals and made their re-printed manuals less complete, for compliance purposes, and in my opinion, this rush to re-print these manuals have produced information that not as safe as the original versions that were required by law.

Access to the diagnostic software of complex medical equipment is absolutely essential for the successful servicing of that equipment. Even though I have a team of 4 highly qualified imaging engineers on staff, they are often at the mercy of the equipment manufacturers to test a simple error code for an x-ray generator, whose testing is included in the 'proprietary' software. I have on my desk (and have included as attachment 1) a service

ticket from General Electric (GE) for $765.00 (dated January 31, 2000) during which they came to my facility expressly to test an error code on an x-ray generator. This is a $765.00 cost to my hospital, and requires my hospital to generate $15,300 in revenue, based upon a 5% net margin. This is clearly NOT in the interest of holding down healthcare costs and assuring compliance with the FDA's performance standards.

Recently, I purchased what GE stated was GE-complete compliant materials for all of my GE manufactured devices. This latest incident shows me that I, in fact, did not receive all of the compliant materials required for this GE x-ray device from GE.

Manufacturers develop software as a part of the development process of new equipment. Indeed, modern medical equipment will not function without the software. It is integral and inseparable from the hardware. When we purchase the system, only a portion of the cost is for the nuts and bolts and hardware. The majority of the cost is for the software – the brains which make it do its work for us and the patient.

It has long been acknowledged in NFPA 99 (National Fire Protection Association) – Standard for Healthcare Facilities (this is a voluntary standard which has been adopted as law in most states, including Georgia), that medical equipment of all types must be accompanied by complete manuals, including comprehensive preventive and corrective maintenance and repair procedures. (NFPA 99-1996, 9-2.1.8.1(m) – attachment 2). NFPA 99 does not explicitly address software, but I believe the rapid evolution of the computer and our increased dependence on software is the only reason it was not mentioned in the earlier versions of NFPA 99.

I have read Siemens Corporation's letter of December 22, 1999 and must respond to several incorrect statements in it.

First, Siemens is focusing on third party servicers in an attempt to turn this into a competitive issue, with them supplying alleged 'valuable intellectual property' to every 'third-party' servicer in the world, assemblers and others. The issue I make is for the end user – the OWNER of the equipment. Please read the word 'OWNER' whenever Siemens uses 'third-party'.

The diagnostic software is NOT private property. When my hospital paid hundreds of thousands of dollars for an imaging system, we purchased all software necessary to make it operate. We also purchased all software, manuals, instructions, diagnostics, calibrations, and illustrations necessary to keep it in a compliant and calibrated, and in a safe state. Many hospitals choose to have the original manufacturer service complex equipment. But for these complex items, the choice of the service provider is not based upon who can do it the best, or the most cost efficiently, or the promptest, but who had the 'proprietary' software (sometimes referred to as RED or class 'D'). There is absolutely no incentive for such a manufacturer to provide competitive pricing, or favorable terms, or any value-added services at all. The economic incentives are formidable for device manufacturer to deny access to complete compliant materials to users. The fear of FDA enforcement against manufacturers is minimal. I have been in this field for 25 years and have seen it countless times.

Second, the idea that basic diagnostic software is inextricably bound to high-level proprietary software is a matter of design rather than necessity. Manufacturers have been unbundling little pieces of their most secret

software for years, as we prove to them that there is no other way to perform the tasks. But each of these small victories is costly, both in real dollars and in time spent. We (the end users) are working at a tremendous disadvantage – we don't know what is available, so we can't make compelling arguments for the release of certain items. And with the tremendous beaurocracy the manufacturers have set up, most hospitals are afraid to even attempt self-service, because they are facing long downtimes or very expensive manufacturer charges if they need some diagnostics that are not on site. When a patient is in need of care, and downtimes are measured in minutes, the thought of a protracted legal battle with a GE or Siemens is unthinkable and acts as a deterrent. Only the most courageous hospitals will try it self-service. Only the best will succeed.

Third, the idea of diagnostic software being an investment is absurd. Diagnostic and calibration software is a necessity for a manufacturer to develop the equipment and see it to market. The area where the manufacturers have financial control is whether to include these costs as a part of the equipment, or to hold it separate in anticipation of large service revenue dollars later. It is easy to see by the resources which the major imaging manufacturers have put into protecting access to these diagnostics that the service revenue dollars are inflated to make up for lower initial product pricing.

Fourth, let me respond also to the statement that diagnostic software is a matter of commercial negotiation. This is patently untrue. There are just 3 or 4 high-end manufacturers of imaging equipment in the world, so for a given application or market, there may just be one which is acceptable. The manufacturers know this, and the individual hospital (even if a member of a

large group purchasing organization) has little power over such items as diagnostic software. I know of no case where General Electric has released its RED level (top secret) software to an end user. So much for negotiating equity.

Fifth, should manufacturers be allowed to include research and development costs in the 'at cost' price? Definitely not. The R&D was a part of their equipment development, and is required by their own service force. Given the unsavory track record of these companies, they are not likely to fairly allocate the costs and are much more likely to shift a disproportionate share of the burden to end users, like my hospital, thus perpetuating the high barrier to self-service which they have already established.

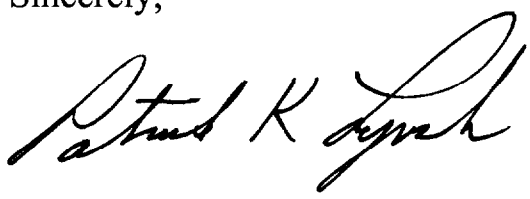
Sixth, does this rule require notice and comment? I think not. The regulations contained in 21CFR have been published for twenty-eight years. Not until Thomas Quinn and others began making it unbearable for manufacturers to stall any more, did they respond directly, as evidenced by the Siemens letter. They waited as long as they could. In the meanwhile, the service revenue dollars kept rolling in. Now they are attempting to stall and delay the process even further, while reaping their restrictive and unlawful service revenues. If the rules required notice and hearings, why are they just now raising the issue?

I am not an attorney, just a biomedical engineer, trying to hold costs down. In doing this, I want to do business with companies who EARN my business by adding value to those things I can do myself. This is possible by reducing my downtime, providing fair pricing, entering into cooperative arrangements whereby we can both prosper, or other creative ways to help

me do my job better than I can alone. But I strongly resent and resist the companies who try to force my business by restricting my access to information and tools which are clearly my legal and ethical right to have.

I request the FDA to use all means available to the FDA to strongly enforce the laws contained in 21CFR immediately and expand its application to all medical devices.

Sincerely,



Patrick K. Lynch, CBET, MBA
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Attachments:

1. GE Medical Systems Service Record for interpretation of error codes
2. Photocopied page from NFPA 99 requiring manuals
3. Letter from Northside Hospital citing State of Georgia Law

GE Medical Systen.. Service Record

Room Number	Dispatch Number	Customer	System ID#
GE R&F 1	0340494884	NORTHSIDE HOSPITAL	404851NRF1

TRIP LOG

Date	Start Time	End Time	System Status	Travel Time	T&L Expense
1/21/2000	13:30	17:00	90	1.0	$0.00

Covered Hours STD Billed

Labor	Travel
3.5	1.0

Non-Covered Hours O.T. Billed

O.T. Labor	O.T. Travel
0.0	0.0

SVC CLS	FMI No.	FMI Code	Model Number	Serial Number	Account Number
001					

SYMPTOM

INTERMITTENT FILAMENT ERROR

DIAGNOSIS AND SERVICE PERFORMED

ASSISTED IN TROUBESHOOTING INTERMITTENT ERRORS DURING HSG STUDIES. FILAMENT ERRORS OCURRING DURING ACQ. SWITCHED TO SMALL FILAMNT FOR ACQ. ERRORS SEEMED TO BEEN ELIMINATED. TOTAL4.5@$170 = $765

PARTS USED

Qty.	Part Number	Consignment No.	Description	Unit Price	Total Price

THANK YOU FOR CHOOSING GE SERVICE. FOR FURTHER ASSISTANCE, PLEASE CALL US AT 1-800-437-1171

Total Charge To Customer	Customer P.O. Number	Accepted By	Serviced By:
			Rick Thompson

This Is Not An Invoice

9-2.1.8 Instruction Manuals and Labels.

9-2.1.8.1 Manuals. The manufacturer of the appliance shall furnish operator's, maintenance, and repair manuals with all units. These manuals shall include operating instructions, maintenance details, and testing procedures.

The manuals shall include the following where applicable:

(a) Illustrations that show location of controls,

(b) Explanation of the function of each control,

(c) Illustrations of proper connection to the patient and other equipment,

(d) Step-by-step procedures for proper use of the appliance,

(e) Safety considerations in application and in servicing,

(f) Difficulties that might be encountered, and care to be taken if the appliance is used on a patient simultaneously with other electric appliances,

(g) Schematics, wiring diagrams, mechanical layouts, parts lists, and other pertinent data for the appliance as shipped,

(h) Functional description of the circuit,

(i) Electrical supply requirements (volts, frequency, amperes, and watts), heat dissipation, weight, dimensions, output current, output voltage, and other pertinent data,

(j) The limits of electrical supply variations — performance specifications of the appliance shall be given for the applicable limits of electrical supply variations,

(k) Technical performance specifications including design levels of leakage current,

(l) Instructions for unpacking (readily available upon opening), inspecting, installing, adjusting, and aligning,

(m) Comprehensive preventive and corrective maintenance and repair procedures.

Where appropriate, the information itemized shall be permitted to be supplied in the form of a separate operating manual and a separate maintenance manual, except that the separate maintenance manual shall also include essentially all the information included in the operating manual.

9-2.1.8.2 Operating Instructions on Appliances. Condensed operating instructions shall be visibly and permanently attached to, or displayed on, any appliance that is intended to be used in emergency situations and that could result in injury or death to the operator or patient if improperly used.

9-2.1.8.3 Labeling. The manufacturer shall furnish, for all appliances, labels that are readily visible and legible and that remain so after being in service for the expected life of the appliance under hospital service and cleaning conditions. Controls and indicators shall be labeled to indicate their function. When appropriate, appliances shall be labeled with precautionary statements. All appliances shall be labeled with model numbers, date of manufacture, manufacturer's name, and the electrical ratings including voltage, frequency, current, and/or wattage of the device. Date of manufacture shall be permitted to be a code, if its interpretation is provided to the user. Appliances shall be labeled to indicate if they (1) are listed for use as medical equipment and (2) have isolated patient leads. Appliances intended for use in anesthetizing locations shall be labeled in an approved manner. (*See 12-4.1.*)

9-2.1.9 Additional Requirements for Special Appliances.

9-2.1.9.1 Signal Transmission Between Appliances.

(a)* *General.* Signal transmission lines from an appliance in a patient location to remote appliances shall employ a signal transmission system designed to prevent hazardous current flowing in the grounding interconnection of the appliances.

(b) *Outdoor Signal Transmission.* Outdoor signal transmission lines from appliances attached to patients shall be equipped with surge protection appropriate to the type of transmission line used. Such appliances or signal transmission lines shall be designed to prevent a hazard to the patient from exposure of the lines to lightning, power contact, power induction, rise in ground potential, radio interference, etc.

9-2.1.9.2 Appliances Intended to Deliver Electrical Energy.

(a) *Conditions for Meeting Safety Requirements.* Electrical-energy-delivering appliances shall conform to the leakage, grounding, and other requirements of this chapter when powered but not delivering energy.

NOTE 1: When delivering energy, such appliances may deviate from these requirements only to the extent essential for their intended clinical function.

NOTE 2: Appliances that intentionally or that might inadvertently apply electrical energy to the patient or to components in contact with the patient require special safety considerations.

NOTE 3: Since there is a wide range of power levels, output frequencies, and purposes of appliances that apply electricity directly to patients or to patient-connected devices, it is not feasible to cite them in detail.

(b) *Specific Requirements by Type of Device.*

1. Electrically Powered Transducers. Exposed metal parts of these devices shall be considered electrodes and meet the applicable requirements of 9-2.1.13, Manufacturers' Tests for Safety of Patient-Care-Related Electrical Appliances. Connectors shall be designed to prevent inadvertent interchange of leads if interchange could constitute a hazard to the patient or operator.

NOTE: Electrically powered transducers include pressure transducers, flowmeters, endoscopes, etc. The electrical energy is not intended to be applied to the patient but to a device that contacts the patient.

2. Patient Impedance Measuring Devices. For a particular application, the combination of frequency and current levels shall limit the applied current to the minimum necessary to achieve the medical purposes, but not to exceed the limits given in 9-2.1.13.5, Lead Leakage Current Tests and Limits, whichever is appropriate.

NOTE: Assessment of physiologic functions by electric impedance measurements usually requires direct contact with the patient and injection of electric current.

3. Electrotherapeutic Devices. Appliances that require specific pulse forms or high power levels shall be designed to protect the operator and attendant personnel from accidental electric shock.

NOTE: Electrotherapeutic devices include devices for electrosleep, electroanesthesia, and electroshock.

NORTHSIDE HOSPITAL

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Dear Sir / Madam:

This letter is to outline the specifications and reasons for operators and technical manuals which Northside Hospital requires for all patient care equipment.

As the end user of medical equipment, Northside Hospital has a right and an obligation to its customers (the patients) to have complete resource manuals available for all medical equipment used in the facility. This is included in our purchasing terms and conditions, and is law by the state of Georgia. The specific requirements are best identified by the NFPA (National Fire Protection Association), Standard for Health Care Facilities, NFPA 99, 1996 edition, which has been adopted as Georgia state law.

As identified in the attached page from the document (page 99-87), a number of manuals are required, including operation and service manuals. The minimum contents of the operator's manuals are detailed in sections a, b, c, d, e, and f. The minimum contents of the service manuals are identified in sections g, h, I, j, k, l, and m.

Northside Hospital recognizes that there may be proprietary information contained in these manuals. We understand that the information is supplied for our use, to maintain equipment at this facility. We agree to abide by every reasonable restriction regarding the use and/or security of the manuals. We will take every necessary safeguard to protect the confidential data provided in these manuals, or learned by our staff in service schools, or other training provided by your company.

Please contact me if I can be of any further assistance.

Sincerely,

Patrick K. Lynch
Director, BioMedical Engineering

(404) 851-6170

NORTHSIDE HOSPITAL

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Form I.D. No. 0215

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1 From This portion can be removed for Recipient's records.

Date 2/22 FedEx Tracking Number 816696289770

Sender's Name Phone

Company NORTHSIDE HOSPITAL V130

Address 1000 JOHNSON FERRY RD NE Dept/Floor/Suite/Room

City ATLANTA State GA ZIP 30342

2 Your Internal Billing Reference Dept #

3 To DOCKETS MANAGEMENT BRANCH

Recipient's Name DIVISION OF MANAGEMENT SYSTEMS AND POLICY OFFICE OF HUMAN RESOURCES AND MANAGEMENT SERVICES Phone

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- [ ] FedEx Priority Overnight — Next business morning
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- [ ] FedEx First Overnight — Earliest next business morning delivery to select locations
- [ ] FedEx 2Day* — Second business day
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* FedEx Letter Rate not available. Minimum charge: One-pound rate

4b Express Freight Service — Packages over 150 lbs. Delivery commitment may be later in some areas.

- [ ] FedEx 1Day Freight* — Next business day
- [ ] FedEx 2Day Freight — Second business day
- [ ] FedEx 3Day Freight — Third business day

Call for Confirmation:

5 Packaging — * Declared value limit $500

- [X] FedEx Letter*
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- [ ] Other Pkg. — Includes FedEx Box, FedEx Tube, and customer pkg.

6 Special Handling

- [ ] Saturday Delivery — Available for FedEx Priority Overnight and FedEx 2Day to select ZIP codes
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- [ ] No
- [ ] Yes — As per attached Shipper's Declaration
- [ ] Yes — Shipper's Declaration not required
- [ ] Dry Ice — Dry Ice, 9, UN 1845 ____ x ____ kg

Dangerous Goods cannot be shipped in FedEx packaging.

- [ ] Cargo Aircraft Only

7 Payment Bill to: Enter FedEx Acct. No. or Credit Card No. below — Obtain Recip Acct. No.

- [ ] Sender — Acct. No. in Section 1 will be billed.
- [ ] Recipient
- [ ] Third Party
- [ ] Credit Card
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Total Packages Total Weight Total Charges

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†Our liability is limited to $100 unless you declare a higher value. See the *FedEx Service Guide* for details.

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